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Pat 1644
PATENT APPLICATION
Docket No.: 2820.1000-000
(BIDMC98-20)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jan E. Schnitzer and Philip Oh

Application No.: 09/208,195

Group Art Unit: 1644

Filed: December 9, 1998

Examiner: M. Tung

For: IMMUNOISOLATION OF CAVEOLAE

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| CERTIFICATE OF MAILING | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 | |
| on <u>04/10/00</u> | <u>Lisa Jensen</u> |
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| Typed or printed name of person signing certificate | |

REPLY TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Responsive to the Office Action dated March 9, 2000, Applicant elects Group I, Claims 1-9, 11-17, 19-22, 24 and 25, drawn to methods of isolating caveolae, with traverse.

Group II (Claims 10, 18, 23 and 26) is drawn to purified caveolae, As indicated in the claims themselves, the purified caveolae of Claims 10, 18, 23 and 26 are prepared by the methods of Claims 1, 11, 19 and 24, respectively; thus, Groups I and II are related as a process of making and product made.

The invention(s) claimed in the subject application pertain to methods of isolating caveolae using immuno-affinity isolation with an antibody that is specific for caveolin and which binds to oligomerized caveolin (caveolin in its native state as an oligomeric structure), and to caveolae isolated by these methods. Caveolae isolated by these methods have very specific characteristics: for example, as indicated in the specification at page 5, lines 4-7, caveolae isolated by these methods retained more caveolae-related proteins than caveolae isolated by other

procedures and were more representative of caveolae in their native state than caveolae isolated by the other procedures.

In order for the inventions of Group I and Group II to be considered distinct, either or both of the following must be shown: first, that the process as claimed can be used to make other and materially different product; or second, that the product as claimed can be made by another and materially different process. The Examiner states that the second characteristic (that the product as claimed can be made by another and materially different process) is applicable because:

the product, the caveolae can be made by isolation of glycolipid GM1, by identification of a Ca^{2+} dependent ATPase, or inositol 1,4,[5]-triphosphate receptor as disclosed on page 2 of the instant specification as being present exclusively in the region of the caveolae.

The Examiner refers to a portion of the "Background of the Invention" which states that caveolae are enriched in caveolin, the glycolipid GM1, the plasmalemmal Ca^{2+} -dependent adenosine triphosphatase, and the inositol 1,4,5-triphosphate receptor, all of which reside on the cell surface almost exclusively in caveolae. Although these four molecules reside in caveolae, their presence in caveolae does not mean that highly purified caveolae as claimed in the present application (or even any caveolae at all) can be isolated solely by performing an isolation of any one of these molecules. The application does not state or imply in any way that the highly purified caveolae of the Group II claims can be made by any method other than by the methods described in the claims of Group II. In fact, the application compares the caveolae of the Group II claims, obtained by the methods of the Group I claims, with caveolae prepared by other methods, and demonstrates that the claimed caveolae have very specific characteristics, such as retention of more caveolae-related proteins than caveolae isolated by other procedures, and better representation of caveolae in their native state than caveolae isolated by the other procedures.

Caveolae are complex microdomains; when investigating the physiological composition and functions of caveolae, it is imperative to use a preparation that presents caveolae in a state that is as close to their native state as possible. Applicant has provided such caveolae in the

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present application, as well as a means for preparing such caveolae. The caveolae of the invention have the special properties described herein because of the unique methods by which they are prepared. Thus, the purified caveolae as claimed in Group II are integrally related to the methods of purifying caveolae of Group I.

In view of these considerations, reconsideration of the restriction requirement is requested.

If the Examiner believes that a telephone conversation would expedite prosecution of the application, the Examiner is invited to call Elizabeth W. Mata at (915) 845-3558. If Elizabeth W. Mata cannot be reached, the Examiner is invited to call Doreen Hogle at (781) 861-6240.

Respectfully submitted,

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